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Retrieval and scientific interpretation of ecotoxicological information

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INFOTOX Document No 017-2025 Rev 3.0: Response to ACB's Comments on the INFOTOX Toxicological Risk Assessment for the Purpose of Derogation of KNERSUS® 200 SL (L10631) (INFOTOX Report No 031-2024 Rev 3.0)

1 Introduction

Scientific documents, and also INFOTOX risk assessment reports, are regularly peer reviewed by other specialists in the relevant fields and it is thus not surprising that the glufosinate ammonium risk assessment reports have been reviewed by third parties. In the case of the INFOTOX reports the expected fields of expertise are Toxicology or Epidemiology.

2 The report by the African Centre for Biodiversity ("ACB")

This INFOTOX document has been compiled in response to the ACB report:
"*Highly hazardous pesticides and GMOs*", dated February 2025, researched and written by ACB research consultant Linzi Lewis.

It is stated that *"(T)he African Centre for Biodiversity (ACB) is committed to dismantling inequalities and resisting corporate industrial expansion in Africa's food and agriculture systems*".

The overall tone of the document is one of mistrust, stating that *"(T)here are deep concerns that too much power is vested in the Registrar, who operates within the mandate of the Department of Agriculture, which ultimately serves the interest of agribusiness and commercial agricultural imperatives."*

The risk assessment paradigm is also not trusted. The author, in principle, rejects the derogation process, stating about risk assessment that *"these arguments and interpretations are false, dangerous, and misleading. They rely on outdated paradigms and data and perpetuate unjust labour practices and environmental racism*".

Detailed responses from INFOTOX are presented in the tables below. Comments from the ACB were copied directly into the table, where required.

ACB COMMENTS		INFOTOX RESPONSE
Summary The legislative framework to regulate chemical remedies in South Africa is outdated, fragmented, and ineffective. Policy and regulatory reforms to date have taken place within a condemned and hopelessly antiquated framework and remain contradictory and untransparent. They maintain a system that consistently and systematically violates the human rights of all South Africans and violates South Africa's 2010 Pesticide Management Policy. Despite regulatory reforms that specify the phase out of HHPs, these regulations provide loopholes to sustain the continued and unconstitutional use of toxic HHPs. We are now confronted with several applications for derogation of GLA, an HHP targeted for phase out, out of 29 such chemicals, concerning which we are submitting these objections.		This statement deals with rejection of the current regulatory system, which is not for INFOTOX to respond to.
Summary 6. The RAs argue that the registrar should grant the derogation of GLA and, therefore, allow for its sustained use. The argument is based on an interpretation that the realistic worst-case conditions are negligible: labelling and PPE are sufficient to prevent or control grave dangers to human health, while the risks to animal and environmental health are a sufficient price to pay for the need to use this HHP – in light of increasing herbicide tolerant weeds – based on Regulation 8(6) of the 2023 Regulations of Act 36. We believe these arguments and interpretations are false, dangerous, and misleading. They rely on outdated paradigms and data and perpetuate unjust labour practices and environmental racism.		The INFOTOX risk assessment is aligned with risk assessment practices of USEPA, as documented in the INFOTOX reports and fully referenced therein. It is incorrect to suggest that the health risk assessment practices and toxicology data are outdated.
1. Overview of pesticide regulation, phasing out of HHPs In South Africa, agricultural remedies are regulated under the Fertilizer, Farm Feeds, Agricultural Remedies, and Stock Remedies Act (Act No.36 of 1947) (Act 36). The Pesticide Management Policy of 2010 was developed in response to this outdated legislation, which largely upheld historical environmental racism.		INFOTOX should not be expected to comment on Act 36 as such, or inferences about environmental racism. This section also deals with substances of concern with hazard classification in CMR categories 1A or 1B, and/or under certain conventions. The GHS deals with hazard classification, not health risks. These concepts are explained in Sections 3 and 4 of the INFOTOX

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		reports, and are aligned with the internationally accepted health risk assessment paradigm.
2. Derogation procedures This is largely a discussion of the derogation process, followed by the statement *"(T)his provides legal means to continue inherently illegal and unconstitutional practices*".		The fact is that glufosinate-ammonium is registered for use in numerous countries around the world for weed control. INFOTOX conducted health risk assessments following international practice.
3. The case of GLA: HHPs, derogation, illegalities, GM crops, and the trajectory of agriculture in SA **3.1. Background to GLA**		There is nothing to comment on in this section.
3.2. Genetically engineered crops and GLA **In this section there is a sub-heading Effects on human and ecosystem health.**		This sub-section presents primarily an overview of toxicology and environmental fate of glufosinate ammonium, which has not been neglected in the INFOTOX risk assessments.
3.3. Classification of glufosinate-ammonium as a highly hazardous chemical		This section deals primarily with glufosinate ammonium as a hazardous chemical according the GHS. It is not clear according to which criteria ACB has concluded that the substance should be termed "highly" hazardous. However, supposing that ACB means that it is classified as an HHP, it is correct that glufosinate ammonium is an HHP, but HHPs are still in use and registered. For this reason, the PCO requirements have been included on the label. All HHPs are sold and handled as Restricted agricultural remedies.
In Section 3.3 there is a sub-section **International guidelines and standards regarding HHPs** From a regulatory perspective, the EU took the lead., in November 2009, it shifted from a paradigm based on an assessment of pesticide risks only, with Regulation 1107/2009/EC, to one that emphasises the need to consider the intrinsic hazards of pesticides. Accordingly, Reg. 1107/2009 stipulated that pesticide substances (active ingredients) proven to be carcinogenic, mutagenic, toxic for reproduction, and endocrine disruptors shall not be authorised in the EU (PAN, 2024). However, despite this, double standards exist whereby the EU		It is uncertain why publication of Regulation 1107/2009/EC should be regarded as a world-wide paradigm shift, with the EU taking the lead, as inferred by ACB. The statement reflects a misunderstanding of the concepts of hazard and risk, which are explained in Sections 3 and 4 of the INFOTOX reports. It is incorrect to say that Regulation 1107/2009/EC stipulated those formulations with active ingredients "*proven to be carcinogenic, mutagenic, toxic for reproduction, and endocrine disruptors shall not be authorised in the EU*" shall not be authorised. The Regulation is very

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continues to export pesticides banned for use on EU soil, including GLA. Despite shifting discourse on HHPs, the paradigm of assessing chemicals based on RA remains largely the same globally.		specific about carcinogenic and reproductive categories in its statement. Nevertheless, a balanced approach, considering also the positions of leading agencies in the world, such as the USEPA, should be considered. As stated in the INFOTOX reports, Karamertzanis et al. (2019)[1] (ten years after publication of the 2009 EC Regulation), evaluated the impact on classifications of carcinogenicity, mutagenicity, reproductive and specific target organ toxicity after repeated exposure in the first ten years of implementation of the REACH[2] regulation. The authors highlighted that classification for carcinogenicity, mutagenicity, reproductive toxicity, and specific target organ toxicity (repeated exposure) ("STOT RE") triggers several obligations for manufacturers, importers, and professional users. The purpose of such obligations is to curtail risks to the occupationally exposed and to the general public, who might be inadvertently exposed, or who might come in contact with potential residues in food and drinking water. Karamertzanis et al. (2019) then stated: "*In addition to such consequences under other legislations* (sic)*, registrants are required to carry out exposure assessment and risk characterisation for substances that are classified and, hence, classification under REACH is a trigger for risk assessment for human health.*" OECD (2021)[3] refers to the European Centre for Ecotoxicology and

[1] Karamertzanis PG, Atlason P, Nathanail AV, Provoost J, Karhu E and Rasenberg M. 2019. The impact on classifications for carcinogenicity, mutagenicity, reproductive and specific target organ toxicity after repeated exposure in the first ten years of the REACH regulation. Regulatory Toxicology and Pharmacology, 106: 303-315.

[2] Registration, evaluation and authorization of chemicals.

[3] OECD. 2021. Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternative, OECD Series on Risk Management, No. 60, Environment, Health and Safety, Environment Directorate, OECD.

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		Toxicology of Chemical's ("ECETOC") Targeted Risk Assessment ("TRA") tool for calculating the risk of exposure from chemicals to workers, consumers, and the environment. This illustrates the logic of basing the final decision about the safety of a chemical or formulation on health risk assessment, rather than only on hazard identification, as represented in the GHS. There are 9 entries referring to "*risk assessment*" in the Regulations, which illustrates the continuing relevance of risk assessment.
3.4. Derogation applications of GLA in South A **3.4.1. Impact of exposure on human health** The applicants rely on the fact that instructions on the label are followed correctly, yet this fails to consider the reality of PPE compliance amongst farmers and farm workers and the precarious conditions of many women and seasonal farm workers in particular. In addition, and crucially important, is the linkage between herbicide use and GE crops, something entirely neglected in the RAs. As an increasing number of crops are approved both for commercial and general release, post-application workers are at increasing risk as pesticides are applied indiscriminately to the harvested product. Despite GLA being characterised as having high reproductive toxicity, based on GHS classification and BASF itself, the RAs completely eradicate any concerns around the hazard itself, based on apparent real-life situations, with adherence to the information on the labels. Yet this risk-based approach fundamentally contradicts the commitment to phase out HHPs so that derogation procedures undermine this process entirely. The paradigm by which these RAs are oriented dilutes the hazardous nature of the chemicals themselves and the precautionary principle and is, therefore, outdated.		The product is for use in large-scale agricultural crop production enterprises. The product is not intended for sale to residential gardeners. The risk assessment states that exposure is considered for occupational pesticide handlers. An employer who uses pesticides in agriculture has a legal obligation to protect employees against exposure and health risks. Sufficient information is provided on labels and safety data sheets. It is uncertain how ACB expects INFOTOX to deal with GE crops in health risk assessments, as this assessment deals with exposure to glufosinate ammonium for spray scenarios described in labels. It is the legal obligation of an employer to avoid indiscriminate application of any pesticide, which implies adherence to supplier instructions on correct application, and precautionary statements to protect human health and the environment. The author of the ACB report disregards the difference between hazard and risk, as described in Sections 3 and 4 of the INFOTOX reports. INFOTOX never disregarded the hazards. There are examples where the precautionary principle was applied despite sufficient risk assessment knowledge to understand the risks. There is nothing outdated about the risk assessment approach. Risk assessments are intended to broaden the assessment of health impacts beyond the initial

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The impact of exposure through food consumption is mostly brushed off because pesticides are not sprayed on the crop itself. There are two problems with this statement. Firstly, as some RAs indicate, GLA is and will be used in potato desiccation (and perhaps other crops). Therefore, GLA is used directly on harvested crops.		identification of hazards. Potato desiccation does not mean spraying glufosinate ammonium directly on the potato tuber, the part of the plant that is harvested and that will be eaten by consumers. Glufosinate ammonium is not sprayed directly on edible parts of crops. It is not necessary to respond to the second comment about GM crops, as this has been dealt with earlier.
3.4.2. Impact on the environment The RAs report that: "The USEPA (2013) preliminary risk assessment did not identify risks of concern for aquatic plants, fish, or aquatic invertebrates, except for the use of glufosinate-ammonium on rice. Considering that the use of glufosinate-ammonium on rice is not relevant in South Africa, it can be concluded that the use of glufosinate ammonium poses no ecological risks or concerns for aquatic organisms." This raises the concern of risk not being adequately considered in other production chains due to limited research.		It is uncertain what is meant with "other production chains". The statement referred to means that risks of concern for aquatic plants, fish, or aquatic invertebrates were found only in the case of rice production. This section in the INFOTOX risk assessment reports deals with risks to non-target aquatic organisms. Considering the extensive USEPA research documents, the suggestion of "limited research" has no valid basis.
3. Concluding remarks Rather, a hazard-based approach, i.e. the property of the compound independent of exposure, following the example taken by the EU, is better aimed at ensuring the rights embedded in the Constitution are centred and realised.		The ACB document is sometimes repetitive. It has not been the intention to respond to each comment in the report, but to provide an overall context of the matter. The author appears to confuse the concepts of hazard and risk, and advocates banning pesticides without consideration of risk assessment. Despite extensive scientific support for the INFOTOX risk assessments, there is a blanket rejection of the reports. It is also troublesome that the Department of Agriculture is portrayed as an irresponsible institution, acting illegally and deliberately promoting unjust labour practices and environmental racism.

Yours sincerely

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